UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES ONLY TO: ***Wave 1 Cases Listed on Attached Exhibit A***	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF ELAINE DUNCAN

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiffs' Motion to Exclude the Opinions and Testimony of Elaine Duncan ("Plaintiffs' Motion") [Dkt. 2033].

In response to Plaintiffs' designation of Anne Wilson and Russell Dunn, Ethicon designated Elaine Duncan as an expert both to rebut Ms. Wilson's and Dr. Dunn's opinions and to testify that Ethicon complied with both U.S. and international design control and risk management standards that apply to the sale of TVT, TVT-O, Prosima, Prolift and Prolift+M. If the Court grants Ethicon's motions to exclude Ms. Wilson and Dr. Dunn, then Ethicon will withdraw its designation of Ms. Duncan, and the Court need not consider the motion to exclude her. But if for any reason the Court should allow Ms. Wilson and/or Dr. Dunn to testify, Ethicon in fairness should be allowed to call Ms. Duncan to set the record straight with respect to compliance to the very same international standards on which Ms. Wilson and Dr. Dunn rely.

Ms. Duncan's testimony is admissible. She is qualified to offer her opinions, and Ms. Duncan applied the proper methodology to arrive at her opinions. Her opinions are relevant to

the facts at issue in this litigation. Accordingly, Ms. Duncan's testimony complies with the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and the Federal Rules of Evidence and should be admitted.

BACKGROUND

Ms. Duncan is the president of Paladin Medical, Inc., a medical device consulting corporation that specializes in product engineering and process analysis, as well as regulatory compliance. Ex. B, Curriculum Vitae 2015 for Elaine Duncan ("Duncan CV") at 1. Her occupational history includes serving as vice president of research and development, vice president of quality assurance, director of regulatory affairs and quality assurance, and senior research engineer for various medical device manufacturers and consultants. *Id.*

Ms. Duncan earned her Bachelor of Science degree in mechanical engineering from the University of Kentucky, and her Master of Science degree in mechanical engineering from the University of Minnesota. *Id.* She is a member of the Society for Biomaterials, serves as an editor of its Biomaterials Forum, and sits on the editorial review board for its Journal of Biomedical Materials Research. *Id.* at 2. She is also a member of the Association for the Advancement of Medical Instrumentation, the American Society for Testing Materials (F-4 committee on medical device standards), the Regulatory Affairs Professional Society, and LifeSciences Alley. *Id.* Ms. Duncan has been certified since 1994 in Regulatory Affairs by the Regulatory Affairs Professional Society. *Id.* Ms. Duncan has published voluminous articles regarding regulatory affairs, medical device design, and medical device design process (*id.* at 3-4), and she has given numerous presentations and speeches on these subjects (*id.* at 4-7). *See also* Ex. C, TVT Report of Elaine Duncan, MSME, RAC ("TVT Report") at 1-4.

In relation to this case, Ms. Duncan reviewed the developmental history and the design control and risk management processes employed by Ethicon in relation to the acquisition of TVT and the design, manufacture, and post-market oversight of TVT, TVT-O, Prolift, Prolift+M and Prosima. Ex. C, TVT Report at 1; Ex. D, TVT-O Report of Elaine Duncan, MSME, RAC ("TVT-O Report") at 1; Ex. E, Prolift, Prolift+M and Prosima Report of Elaine Duncan, MSME, RAC ("POP Report") at 1. Specifically, her reports discuss the manner in which medical devices are developed, from the initial concept through post-market monitoring. Ex. C, TVT Report at 4-8; Ex. D, TVT-O Report at 4-8; Ex. E, POP Report at 6-9. She discusses the standards applicable to these processes, including both the standards applicable in the United States and the foreign standards. *Id*.

Also, Ms. Duncan examines the relationship between the various standards and the regulatory framework of the jurisdictions in which the product is intended to be sold. Ex. C, TVT Report at 8-10; Ex. D, TVT-O Report at 8-10; Ex. E, POP Report at 9-11. Next, she reviews the actual processes that Ethicon engaged in when acquiring, designing, manufacturing, and monitoring TVT, TVT-O, Prolift, Prolift+M and Prosima and analyzed whether Ethicon's activities complied with the applicable standards. Ex. C, TVT Report at 10-23; Ex. D, TVT-O Report at 10-27; Ex. E, POP Report at 11-16. Ultimately, Ms. Duncan concludes that Ethicon complied with the applicable standards. Ex. C, TVT-Report at 23; Ex. D, TVT-O Report at 27-28; Ex. E, POP Report at 15-16.

Lastly, Ms. Duncan examined the reports of Plaintiffs' designated experts – Anne Wilson and Russell Dunn – and offers rebuttal opinions pointing out the errors in Ms. Wilson's and Dr. Dunn's analyses. Ex. C, TVT Report at 23-55; Ex. D, TVT-O Report at 28-51; Ex. E, POP Report at 16-36.

With limited exceptions discussed below, Plaintiffs' Motion does not contest Ms. Duncan's qualifications and methodology used to offer these opinions. Plaintiffs' Motion does not challenge Ms. Duncan's opinion that Ethicon's design control and risk management processes complied with the foreign standards and regulations on which Plaintiffs' own experts relied. With very limited exceptions, Plaintiffs' Motion does not challenge Ms. Duncan's rebuttal to Ms. Wilson's and Dr. Dunn's opinions.

Rather, Plaintiffs argue: (1) that Ms. Duncan should not be allowed to discuss the applicable United States standards for design control and risk management processes; (2) that Ms. Duncan did not apply her usual methodology with respect to some of her opinions; (3) that certain opinions lack sufficient foundation; (4) that Ms. Duncan should not be allowed to offer medical opinions; (5) that Ms. Duncan should not be allowed to opine regarding the AUGS position statement in a POP case; (6) that Ms. Duncan's rebuttal opinions to Dr. Dunn are outside her area of expertise; and (7) that Ms. Duncan did not apply a discernible methodology. Each of Plaintiffs' arguments is without merit, and their Motion should be denied.

ARGUMENT

I. Standard for admissibility of expert opinion testimony.

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 U.S. Dist. LEXIS 92316, at *3-8 (S.D.W. Va. July 8, 2014).

II. Design control and risk management process is too intertwined with governmental regulatory requirements to allow testimony and evidence on the subject without permitting a discussion of 21 C.F.R. 820.

The medical device design control and risk management processes are highly regulated. *See* Ex. C, TVT Report at 8-10. Though efforts were made to create a global design control

process, these failed due to the pervasive nature of the regulatory schemes applicable to medical devices.

As a result, there is no "industry standard" for medical device design control and risk management processes separate and apart from governmental regulation. *Id.* Accordingly, the most critical question when evaluating the design control and risk management processes is: in what jurisdiction is the medical device intended to be sold? Once the jurisdiction is identified, the applicable design control and risk management standard can be identified.

The underlying dispute in this case arises from the sale of Ethicon's TVT and TVT-O stress urinary incontinence devices and Prolift, Prolift+M and Prosima pelvic organ prolapse devices in the United States. The standard for design control and risk management processes of medical devices in the United States is the FDA's Quality Systems Regulation, 21 C.F.R. 820.1, *et seq.* and associated FDA guidance documents. Accordingly, Ms. Duncan opines the FDA's Quality Systems Regulation, together with the FDA guidance publications and the FDA recognized consensus standards, is the only design control and risk management standard applicable to medical device manufacturers in the United States. Plaintiffs' expert *agrees*. Ex. F, Anne Wilson 9/17/15 Dep. Tr. 69:23-70:16. Yet Plaintiffs' expert ignores the jurisdictional questions and opines that Ethicon failed to comply with the European regulations.

As more fully addressed in Ethicon's Memorandum in Support of Defendants' Motion to Exclude the Opinions and Testimony of Anne Wilson [Dkt. 2086 at 4-11], Ms. Wilson deliberately avoided a discussion of the FDA's Quality Systems Regulation. Instead, she analyzed Ethicon's design control and risk management process under the European regulations, despite the fact that Ms. Wilson admits that the European regulations have never been adopted in the United States (Ex. F, Anne Wilson 9/17/15 Dep. Tr. 180:1-180:21).

If Ms. Wilson's testimony is allowed, Ms. Duncan should be allowed to rebut it not only by addressing the very same foreign regulations on which Ms. Wilson relies, but also by addressing the FDA regulations that govern this subject in the United States.

III. The FDA design control regulations concern the safety and efficacy of TVT and so are relevant and admissible even if the Court should continue to exclude 510(k) evidence.

A. Ms. Duncan's testimony that Ethicon complied with the FDA design control regulations concerns the safety and efficacy of TVT and, thus, is relevant.

Plaintiffs wrongly seek to extend to this evidence this Court's prior ruling excluding evidence regarding the 510(k) clearance process as irrelevant specifically "[b]ecause the FDA's 510(k) clearance of the TVT does not speak to its safety or efficacy." *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 755 (S.D.W. Va. Jan. 15, 2014) (emphasis added).

But the FDA's "regulations" governing medical devices are far broader than the 510(k) clearance process. *Compare* 21 C.F.R. § 800.10-898.14 (complete listing of medical device regulations), *with* 21 C.F.R. § 807.81-.100 (regulations regarding the 510(k) process). Even if the Court's ruling with respect to 510(k) stands, the 21 CFR Part 820 design control and risk management regulations operate on a wholly different basis from 510(k) clearance. The regulations speak directly to safety, i.e. the monitoring of risk. They are not merely a question of equivalency to the past. They are on-going, and do not just represent a snapshot in time. And they require ongoing audits, not just a single agency review. In fact, it is possible to testify to compliance with them without even mentioning 510(k).

To be more specific, whereas the Court found that the 510(k) process went to the question of "equivalence" and not "safety and efficacy," the Quality Systems Regulation expressly concerns safety and efficacy. As the regulation states, "[t]he requirements in this part

[21 C.F.R. 820] are intended to ensure that finished devices will be safe and effective . . . ." 21 C.F.R. § 820.1 (emphasis added).

Accordingly, Ms. Duncan's opinions based on the Quality Systems Regulation fall outside both the letter and the logic of the Court's prior order.

B. Ms. Duncan's references to the 510(k) process can be excluded without altering her overall opinions and testimony.

In her report, Ms. Duncan notes that when Ethicon made its 510(k) submission to the FDA regarding TVT, Ethicon outlined its application of the Quality Systems Regulation and the FDA approved the 510(k) submission. Plaintiffs argue that all of Ms. Duncan's opinions are "so intertwined" with the 510(k) clearance process that they all must be excluded.

Ms. Duncan's opinions do not rely on the 510(k) process or Ethicon's submissions to the FDA pursuant to the 510(k) process. The reference in her report to the 510(k) process can be excluded without causing any change to her opinions.

Ms. Duncan's report admittedly uses the term "510(k)" in several instances. She did not rely on the 510(k) submissions, however, to arrive at her opinions concerning Ethicon's compliance with the Quality Systems Regulations. *See* Ex. G, Dep. of Elaine Duncan ("Duncan Dep.") at 179:17-179:23.

> Q. . . . [Y]ou have relied on the federal regulations and the 510(k) process as part or as one of the bases for your conclusion that Ethicon acted appropriately in bringing the TVT to market; correct?
>
> A. I considered it as one. I didn't rely on it.

Id.; *see also id.* at 186:13-186:16 ("I did not do an extensive review of the 510(k). I did a cursory review for content and noticed that the FDA had accepted it. I did not try to do due diligence on the 510(k).").

Device manufacturers will note in their 510(k) submission that they complied with the FDA's Quality Systems Regulation. Ms. Duncan points out in her reports that Ethicon included such a statement in its 510(k) submission and that the FDA accepted the 510(k) submission as complete. *See, e.g.*, Ex. C, TVT Report at 12-13.

Ms. Duncan did not rely on the FDA's acceptance of the 510(k) submission as evidence that Ethicon complied with the Quality System Regulation. Ex. G, Duncan Dep. at 179:17-179:23. Instead, Ms. Duncan performed her own review and analysis of Ethicon's compliance with the Quality Systems Regulation and arrived at her own independent conclusion that Ethicon complied with the regulations. *Id.* at 172:22-173:11. In other words, the FDA's acceptance of the 510(k) submission is consistent with Ms. Duncan's opinions in this case, but the FDA's acceptance of the 510(k) submission is not a basis for Ms. Duncan's opinions.

Second, Ms. Duncan unequivocally testified that removing references to the 510(k) process from her report would not alter her conclusions. *See* Ex. G, Duncan Dep. at 180:17-180:19. "If you chose to throw every reference I've made to the 510(k) out of this report, my conclusions would be the same." *Id.*

Plaintiffs rely on a language trick to claim she did not say this. They cite Ms. Duncan's testimony that the FDA regulations (i.e., the singular governing standard in the United States) cannot be ignored and pretend that when she said "regulations" she meant 510(k). *See* Pls.' Mot. [Dkt. 2036] at 6. Such is not the case. Ms. Duncan has clearly and unequivocally opined that she can exclude all references to the 510(k) process without any alteration of her conclusions.

If the Court deems that references to the 510(k) process are inadmissible, Ms. Duncan can simply and easily excise the statements about the 510(k) process from her testimony.

C. The FDA regulation of medical devices, including the 510(k) process, is relevant and should be admitted.

Ethicon recognizes the Court's prior order excluding evidence regarding the FDA's 510(k) clearance process as irrelevant. Without further belaboring prior briefing, Ethicon respectfully re-submits that the 510(k) process is relevant and evidence of TVT's 510(k) clearance should be admitted.

IV. Ms. Duncan's Methodology Is Reliable

Plaintiffs argue that if Ms. Duncan is allowed to testify concerning her opinions regarding Ethicon's compliance with the very same European regulatory standards on which Ms. Wilson and Dr. Dunn relied, then her opinions will not be reliable because she will not be applying her usual methodology of referencing the FDA's Quality System Regulations, 21 CFR Part 820. If the Plaintiffs' position were correct, then the same could be said of Anne Wilson since she relies on FDA guidance documents "all the time," just not in her TVT, TVT-O and TVT-S reports in this case. Ex. H, Wilson 3/22/16 Dep. Tr. 56:1-22. Anne Wilson admits that in the United States experts performing the analysis that both she and Elaine Duncan performed apply the FDA's Quality System Regulations and guidance documents. Ex. F, Anne Wilson 9/17/15 Dep. Tr. 69:23-70:16.

If the Court rules that the jury cannot consider whether Ethicon complied with the applicable FDA Quality Systems Regulations, then a perhaps unintended consequence is that it will not be possible for any legitimate quality systems compliance expert for a product marketed in the United States to apply his or her usual methodology in this case. However, that decision would have no bearing on whether Elaine Duncan applied her usual methodology in evaluating Ethicon's compliance with the standards on which the Court does allow testimony. Ms. Duncan's reports demonstrate her expertise in the application of the very same European

standards on which Anne Wilson and Russell Dunn rely, ISO 9001, EN46001, EN1441, ISO 13485 and ISO 14971. *See, e.g.*, Ex. C, TVT Report at 7-9, 11-16, 26-54. Plaintiffs' motion nowhere suggests that Ms. Duncan failed to properly apply these standards.

V. Ms. Duncan's Opinions Have a Sufficient Foundation

Plaintiffs argue that Ms. Duncan lacks sufficient knowledge and qualification for her opinion that it was proper for Ethicon to "assess[] the risk of the TVT-R and TVT-O devices together." First, Plaintiffs argue that in order for Ms. Duncan to express this opinion she must know whether TVT-R and TVT-O have the exact same risk profile. Second, Plaintiffs argue that Ms. Duncan knowledge of differences between the two devices is not accurate. Plaintiffs are wrong on both points.

In order to place Plaintiffs' argument in proper context, some background is needed. In 2007 Ethicon adopted a new risk management plan that called for the generation of a "risk management report" for "legacy" devices, that is, devices marketed prior to the latest ISO 14971 standard. Ex. I, Risk Management Plan at 2. The plan on its face provided that similar devices may be grouped together in a single risk management report. *Id.* TVT and TVT-O were "legacy" devices, and as stated in the plan, Ethicon prepared a single risk management report covering both devices. Ex. J, Risk Management Report for TVT and TVT-O. Plaintiffs' expert, Anne Wilson, opined that it was improper for Ethicon to include TVT and TVT-O in the same risk management report. Ex. K, Anne Wilson Report at 22. Ms. Wilson cited EN 1441, ISO 14971:2000 and ISO 14971:2007 as authority for her position.

There is nothing in these cited standards that required Ethicon to write a separate risk management report for TVT and TVT-O. ISO 14971:2007 expressly addresses risk management plans and expressly approves grouping categories of a device:

> Criteria for risk acceptability are derived from the manufacturer's policy for determining acceptable risk (see D.4). The criteria can be common for similar categories of medical device. Criteria for risk acceptability can be part of the manufacturer's established quality management system, which can be referenced in the risk management plan (see for example ISO 13485:2003[8], 7.1).

Ex. L, ISO 14971:2007 at 55.

Likewise, ISO 14971:2007 expressly emphasizes the importance of utilizing information for similar products when conducting a risk analysis:

> NOTE 1 If a risk analysis, or other relevant information, is available for a similar medical device, that analysis or information can be used as a starting point for the new analysis. The degree of relevance depends on the differences between the devices and whether these introduce new hazards or significant differences in outputs, characteristics, performance or results. The extent of use of an existing analysis is also based on a systematic evaluation of the effects the changes have on the development of hazardous situations.

Id. at 9.

> NOTE 5 The scope of the risk analysis can be very broad (as for the development of a new device with which a manufacturer has little or no experience) or the scope can be limited (as for analysing the impact of a change to an existing device for which much information already exists in the manufacturer's files).

Id.

> **A.2.4.1 Risk analysis process**
>
> The second paragraph describes how to deal with the availability of a risk analysis for a similar medical device. The note informs users of this International Standard that when adequate information already exists it can and should be applied to save time, effort and other resources. Users of this International Standard need to be careful, however, to assess systematically the previous work for applicability to the current risk analysis.

Id. at 19.

One of the reasons it can be appropriate to analyze jointly the risk of products in the same family is that in a risk analysis components are analyzed one at a time. *Id.* at 57. Thus, any differences in the components will be accounted for. Nothing in these standards requires that two categories of a medical device must have the exact same risk profile in order to be considered together.

Ms. Duncan's opinion that it was proper for Ethicon to prepare a single risk management report for TVT and TVT-O is simply a rebuttal to Ms. Wilson's opinion to the contrary. Ms. Duncan properly applied ISO 14971. The implant for both TVT and TVT-O are the exact same

Prolene mesh device. Ex. J, Risk Management Report for TVT and TVT-O at 2-3; Ex. M, Product Description Document at 1-2. The indications for TVT and TVT-O are the same, and when the surgery is complete, the device is located under the midurethra regardless whether it is TVT or TVT-O. *Id.* The difference between the two devices is the method and instruments by which the device is placed in the body. *Id.* Ms. Duncan's report and deposition testimony are entirely consistent and demonstrate a reasonable understanding of the similarities and differences between TVT and TVT-O. Ex. C, TVT Report at 42-42; Ex. N, Elaine Duncan 3/31/16 Dep. Tr. 123:18-127:14.

VI. Ms. Duncan's Opinions Do Not Contain Clinical Conclusions But Rather Are a Proper Application of Published Clinical Literature to the Applicable Standard.

Neither Ms. Duncan nor Ethicon contends that Ms. Duncan should be allowed to offer medical opinions regarding TVT. And, in fact, Ms. Duncan has not attempted to offer such an opinion. Plaintiffs' contention that Ms. Duncan is attempting to offer "clinical conclusion" is based upon a gross misunderstanding of the design control and risk assessment process.

The design control and risk management process involves an ongoing monitoring of post-market experiences reported to the manufacturer. *See, e.g.,* Ex. C, TVT Report at 13-14. Even the regulations cited by Plaintiffs' expert require device manufacturers to consider the clinical history of the device when conducting a risk assessment. *See id.* at 11 (discussing application of the European standards cited by Ms. Wilson). In furtherance of this post-market obligation, Ms. Duncan points to the AUGS position statement, which supports the use of TVT as a safe and effective device for the treatment of stress urinary incontinence. *Id.*

Ms. Duncan does not opine that the AUGS position statement is substantively correct. What she says is that the AUGS statement is a valuable piece of post-market clinical history that Ethicon should take into account when performing its ongoing risk assessments, just like the

other clinical evaluation reports/clinical expert reports. *Id.* ISO 14971:2007 specifically requires that Ms. Duncan evaluate Ethicon's risk management in the light of the current "state of the art":

D.4 Risk evaluation and risk acceptability

This International Standard does not specify acceptable risk. That decision is left to the manufacturer. Methods of determining acceptable risk include, but are not limited to, the following:

— using applicable standards that specify requirements which, if implemented, will indicate achievement of acceptability concerning particular kinds of medical devices or particular risks;

— comparing levels of risk evident from medical devices already in use;

— evaluating clinical study data, especially for new technology or new intended uses;

taking into account the state of the art and available information such as technology and practice existing at the time of design.

"State of the art" is used here to mean what is currently and generally accepted as good practice. Various methods can be used to determine "state of the art" for a particular medical device. Examples are:

— standards used for the same or similar devices;

— best practices as used in other devices of the same or similar type;

— results of accepted scientific research.

Ex. L, ISO 14971:2007 at 39-40.

Ms. Duncan did not, as Plaintiffs wrongly suggest in their Motion, "utilize [the AUGS statement] as the foundation for her opinions." Pls.' Mot. [Dkt. 2036] at 12. Even a cursory review of Ms. Duncan's reports reveals that the AUGS position statement plays only a minor role in her analysis of compliance with both the Quality System Regulations and ISO 14971 for TVT, TVT-O and POP. It is one piece of evidence among many that must be considered in the overall evaluation of Ethicon's risk management process.

VII. Ms. Duncan's Opinions Concerning the AUGS Position Statement Are Relevant to Her POP Report.

Plaintiffs argue that Ms. Duncan should not be permitted to opine concerning the AUGS position statement in a POP case since the position statement relates only to SUI devices such as TVT and TVT-O. Ms. Duncan's POP Report, Ex. E at 12, does reference the AUGS position

statement because the POP devices use Prolene in the mesh as does the TVT and TVT-O devices. This is significant because Plaintiffs make the same degradation argument in their POP cases as they do in their SUI cases. The AUGS position statement is relevant to the question as to whether Prolene in the POP devices is a suitable material for long term implant under ISO 14971, as discussed above.

VIII. Ms. Duncan Does Not Intend to Offer Chemical Engineering and Polymer Science Opinions

Plaintiffs argue that the fact that Ms. Duncan has been designated to rebut Russell Dunn necessarily means that she intends to offer opinions concerning chemical engineering and polymer science. That is not the case. Russell Dunn himself testified that there are two divisions of his report – one concerns the chemical properties of polypropylene and the other concerns quality systems and risk management. Ex. O, Dunn 3-7-16 Dep. Tr. 128:1-130:12. Ms. Duncan addresses only the latter.

Ms. Duncan does opine that "reduction in mesh strength in a normal biologic environment after tissue healing occurs is not viewed as a defect; it can be viewed as a design attribute." Ex. E, POP Report at 25. However, this is not based on any supposed chemical engineering expertise. Rather, it is based on the fact that some meshes such as Prolift+M are intentionally designed to partially degrade over time after implantation. *Id.*

IX. Ms. Duncan Applied a Rigorous Methodology for Her POP Report

Plaintiffs challenge Ms. Duncan's methodology for her POP Report, Ex. E, quoting only a simplistic question and answer from her deposition:

> Q. With respect to the Prolift and the Prolift+M, did you review the entire design history files for both?
>
> A. I reviewed the documents that I was given, yes, sir.

Plaintiffs imply that this leaves open the possibility that Ms. Duncan based her opinions on something less than the entirety of the design history files and CE Mark technical files for TVT, TVT-O, Prolift, Prolift+M and Prosima. If this had indeed been the case then Plaintiffs should have shown the Court that the Bates numbered design history files provided to Ms. Duncan and listed in her reports and reliance lists where somehow incomplete. Plaintiffs cannot do this because they know the files provided to Ms. Duncan were in fact complete.

Plaintiffs also make much ado over the fact that in her POP Report Ms. Duncan did not provide a detailed analysis supporting her findings concerning Prolift and Prolift+M. It should be noted, however, that Plaintiffs made no mention of Ms. Duncan's POP Report concerning Prosima. *See*, Ex. E., POP Report at 14-16. Ms. Duncan's Footnote 24 explains that her analysis of Prosima also applies to Prolift and Prolift+M. *Id. at* 14. It is true that Ms. Duncan's report did not provide the same detailed analysis for Prolift and Prolift+M as she did for Prosima and instead cited the voluminous records concerning these products, but that is because she expressly opined that these records showed the same level of compliance as Ethicon's Prosima records which she did discus in more detail.

Unlike Plaintiffs' expert who disregarded her non-litigation skills in favor of her "expert report skills" (Ex. F, Wilson 9/17/15 Dep. Tr. 41:12-41:15), Ms. Duncan actually applied the generally accepted due diligence review of Ethicon's design control and risk management processes to arrive at her opinions (*see generally, e.g.,* Ex. C, TVT Report).

X. Plaintiffs Do Not Challenge Ms. Duncan's General Qualifications and Numerous Additional Opinions.

Nowhere in Plaintiffs' Motion do they raise any arguments that Ms. Duncan lacks the requisite qualifications to offer design control and risk management opinions. *See generally* Pls.' MIS of Mot. [Dkt. 2036]. Ms. Duncan's curriculum vitae and her nearly four decades of

experience in the field of medical device development speak for themselves. There is no colorable argument that Ms. Duncan is not a bona fide expert in her field.

Additionally, though Plaintiffs seek to exclude Ms. Duncan's opinion testimony in its entirety, there are numerous individual opinions offered by Ms. Duncan for which Plaintiffs' have not argued exclusion.

The two most notable examples of opinions as to which no objection is made are Ms. Duncan's application of the very same European regulations on which Ms. Wilson and Dr. Dunn rely to the facts of this case and the rebuttal to Ms. Wilson's and Dr. Dunn's opinions concerning these European regulations.

Ms. Duncan correctly opines that the only design control and risk management standards applicable in the United States are the FDA regulations. Ms. Duncan does review the European and Canadian regulations, however, and offers opinions regarding Ethicon's compliance with those foreign standards. *See, e.g.*, Ex. C, TVT Report at 5-12. Plaintiffs have not challenged any portion of these opinions. Regardless of whether the Court denies or grants Plaintiffs' Motion, Ms. Duncan should be permitted to offer these opinions as they form no basis of Plaintiffs' Motion.

Beginning at page 23 of her TVT Report, Ex. C. and at page 28 of her TVT-O Report, Ex. D, Ms. Duncan offers an analysis and rebuttal of Ms. Wilson's opinions in this matter. Plaintiffs make no arguments for the exclusion of Ms. Duncan's rebuttal opinions. Accordingly, Ms. Duncan should be permitted to rebut Ms. Wilson's opinion testimony regardless of whether the Court finds for Ethicon or Plaintiffs on the instant motion. Beginning at page 16 of her POP Report, Ex. E, Ms. Duncan offers an analysis and rebuttal of Dr. Dunn's opinions in this matter. Plaintiffs make no arguments for the exclusion of Ms. Duncan's rebuttal opinions concerning

quality systems and risk management. Accordingly, Ms. Duncan should be permitted to rebut Dr. Dunn's opinion testimony regardless of whether the Court finds for Ethicon or Plaintiffs on the instant motion.

CONCLUSION

For all of these reasons, if Ms. Wilson and/or Dr. Dunn are allowed to testify as to "industry standards" based on inapplicable foreign regulations, then Ms. Duncan should be allowed to rebut them and to discuss the FDA regulations which actually govern design control and risk management process in the United States.

If the Court should grant Ethicon's motion to exclude Ms. Wilson's and Dr. Dunn's testimony, Ethicon is willing to withdraw Ms. Duncan as a witness. Ethicon prays for any additional or further relief to which it may be entitled.

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
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CERTIFICATE OF SERVICE

I, Christy D. Jones, certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON